भारतीय मानक
Indian Standard

IS 10148 : 2023

खाद्य सामग्री, औषधि और पैयजल के संपर्क में आने वाले पोलिविनाइल क्लोराइड (पीवीसी) घटकों और सहबहुलकों की वास्तविक सूची

(पहला पुनरीक्षण)

Positive List of Constituents of Polyvinyl Chloride (PVC) and Its Copolymers in Contact with Foodstuffs, Pharmaceuticals and Drinking Water

(First Revision)

ICS 67.250; 83.080.20

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Plastics Sectional Committee, PCD 12

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on the recommendation of the Plastics Sectional Committee and approval of the Petroleum, Coal and Related Products Division Council.

Plastics are now being used on a large scale for packaging of foodstuffs and pharmaceuticals. Where direct contact occurs between the packed commodity and the plastics, the high-molecular-mass polymer itself does not pose a toxic hazard being inert and essentially insoluble in food. There is, however, a likelihood that some transfer will occur of polymer additives, adventitious impurities, such as monomers, catalyst remnants and residual polymerization solvents and of lowmolecular mass polymer fractions from the plastics into the packaged material with consequent toxic hazard to the consumers. The occurrence of acute toxicity due to plastics materials in contact with food is most unlikely, since only trace quantities of potentially toxic materials are likely to migrate. However, the accumulation of these toxic materials with time may lead to hazards which may be serious.

This standard was originally published in 1982. In this revision, the list of constituents have been aligned with international practices like USFDA, EEC directives, REACH etc.

This standard is intended to be used with a series of Indian Standards on plastics for food contact applications which are given in Annex A.

It is emphasized that these standards need to be used in combination to provide a system of control to the manufacturers of plastics as well as the fabricators of thermoplastics packaging materials to derive maximum benefit also serve, it may also serve as basis for official agencies to frame suitable legislation to ensure effective safeguards for the safety and health of consumers where thermoplastics for food contact and related applications are concerned.

The composition of the Committee responsible for the formulation of this standard is listed in Annex B.

Indian Standard

POSITIVE LIST OF CONSTITUENTS OF POLYVINYL CHLORIDE (PVC) AND ITS COPOLYMERS IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

(First Revision)

1 SCOPE

1.1 This standard covers positive list of constituents of PVC, namely, the polymers, copolymers, manufacturing residues and necessary additives which may be regarded as safe for use, when properly processed in contact with foodstuffs, pharmaceuticals and drinking water and when present in the prescribed limits of concentration.

1.2 The positive list does not purport to establish the suitability of the ingredient singly in a particular foodstuff from other than toxicological considerations.

2 REFERENCES

The standards, listed below contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

IS No.	*Title*
IS 9833 : 2018	List of colorants for use in plastics in contact with foodstuffs and pharmaceuticals (*second revision*)

3 TERMINOLOGY

3.1 Polyvinyl Chloride

It shall include:

a) The homopolymers of vinyl chloride;

b) Copolymers containing at least 50 percent by mass of vinyl chloride with one or several of the following monomers:

1) Vinylidene chloride;
2) Acrylonitrile;
3) Styrene and substituted styrene;
4) Butadiene;
5) Ethylene;
6) Propylene;
7) Di-vinyl benzene;
8) Vinyl acetate and vinyl propionate;
9) Maleic, fumaric, itaconic, crotonic, acrylic and methacrylic acids (*Max* limit of 8 percent by mass of all these monomers);
10) Esters of maleic, itaconic, crotonic, acrylic and methacrylic acids with saturated monohydric aliphatic alcohols;
11) Modified PVC basic polymers and its analogous polymers: Chlorinated PVC (69 percent Cl. content *Max*) vinyl chloride co-polymerised with vinyl alcohol and vinyl acetate;
12) Vinyl chloride — poly urethane graft copolymer (with *Min* 50 percent of vinyl chloride inthe final polymer);
13) Vinyl chloride — ethylene copolymer chlorinated [not exceeding 71 percent (w) Cl Content];
14) Alfa Olefins;
15) Vinyl alcohol; and
16) Alkyl vinyl ether.

c) Mixtures of homopolymers of vinyl chloride with one or several of the copolymers indicated in (b);

d) Mixtures of several copolymers indicated in (b); and

e) Chlorinated PVC resin and its compounds with chlorine content < = 71 percent.

4 REQUIREMENTS

4.1 Basic Resin

The polymers and copolymers defined in **3.1a), 3.1b)** and **3.1e)** shall be made in such a way that they contain no ingredients or residues of ingredients used in their manufacture other than those listed in **4.1.1** and **4.2** to **4.8.4**.

4.1.1 The following may be added to polyvinyl chloride (PVC), provided percent by mass content of vinyl chloride of the mixture is at least equal to 50 percent and they conform to the concerned specification:

a) Homo and copolymers of monomers mentioned in **3.1 a)** and **3.1 b)**;

b) Chlorinated polyolefin with a maximum chlorine content of 56 percent by mass;

c) Copolymers of butyl acrylic and vinyl pyrrolidone (with 95 percent by mass of butyl acrylate);

d) Polyurethanes of molecular mass 40 000 to 100 000 obtained from:

   1) Diisocyanate 1,6 hexane;
   2) Diisocyanate 2,4 toluene;
   3) Diisocyanate 2,6 toluene and their mixtures;
   4) Butane dihydric alcohol 1,4;
   5) Polyester resulting from the action of adipic acid on a glycol; and
   6) Addition compounds of propylene or ethylene oxide and/or ethylene with ethylene glycol or poly propylene-glycol or glycerine or trimethylol propane or pentaerythritol or sorbitol.

NOTE — These products should be free from isocyanates and primary amines.

4.2 Catalysts/Initiators

The total residues of catalyst and their decomposition products shall be not more than 0.25 percent by mass of the finished polymer. The residues as well as its decomposed products of the following may be present:

a) Benzoyl peroxide;

b) Aliphatic acid (C_3 to C_{16}) peroxide;

c) tert-Butyl perbenzoate;

d) p-tert-Butyl perpivalate;

e) Methyl ethyl ketone peroxide;

f) Persulphates of ammonium and potassium;

g) Percarbonates of the structure $R_1OCOOOOCOR_2$ where R_1 and R_2 are alkyl, aryl, alkylaryl, alkoxy, alkoxy alkyl or halogen substituted alkyl, aryl, alkylaryl, alkoxy or alkoxy alkyl (C_3 to C_{10});

h) Cycloalkyl (C_5 to C_8) peroxy dicarbonate;

j) bis-4-tert-Butyl cyclohexyl-peroxydicarbonate;

k) Acetyl cyclohexyl sulphonyl peroxide; and

m) Peresters of the structure R_1COOOR_2, where R_1 and R_2 are alkyl, aryl, alkylaryl, alkoxy,or halogen substituted alkyl, aryl, alkylaryl, or alkoxy (C_2 to C_{10}).

4.3 Polymerization Inhibitors

The residue of the polymerization inhibitors shall not exceed 0.01 percent by mass of the finished polymer.

4.4 Emulsifying Agents

The total residues of emulsifying agents shall be not more than 3.0 percent by mass of the finished polymer. The residues of the following emulsifying agents may be present:

a) Alkyl, aryl and alkylaryl sulphates of sodium, potassium and ammonium, the alkyl group containing C_{10} to C_{20};

b) Alpha hydroxy octadecane sodium sulphonate;

c) Sodium, potassium and ammonium salts of sulpho-succinic acid and its mono and di-esters with saturated monophydric aliphatic alcohols C_4 to C_{20};

d) Sodium, potassium and, ammonium salts of saturated aliphatic acids above C_7;

e) Esters of sorbitol or of sorbitan with saturated or unsaturated aliphatic acids above C_7;

f) Calcium, sodium, potassium and ammonium salts of hydroxylic fatty acids C_{12} to C_{20} and their sulphonyl or acetyl derivatives;

g) Products of condensation of ethylene oxide with monobasic aliphatic acids C_{12} to C_{20} and their ammonium sulphates;

h) Products of condensation of ethylene oxide with monohydric aliphatic alcohols C_{12} to C_{20} and their sodium and ammonium sulphates;

j) Products of condensation of ethylene oxide with alkylphenols having alkyl groups C_7 and above and their sodium and ammonium sulphates;

k) Products of condensation of ethylene oxide with alkyl and dialkyl amines C_1 to C_{20};

m) Fatty alcohols C_{10} to C_{20}; and

n) Alkyl, aryl, alkylaryl, acyl, polyethoxy ethanol and their sulphate.

4.5 Suspension Agents

The total residues shall not be more than 1.0 percent by mass of thefinished polymer. The residues of the following may be present:

a) Methylcellulose;

b) Hydroxy ethyl cellulose;

c) Hydroxy propyl methyl cellulose;

d) Sodium carboxy methyl cellulose;

e) Methyl ethyl cellulose;

f) Polyvinyl alcohol (having a viscosity of at least 4 centipoises at 20 °C in 4 percentaqueous solution);

g) Polyvinyl pyrrolidone and copolymers of vinyl pyrrolidone with vinyl ethers or esters; and

h) Copolymers of vinyl alkyl (C_1 to C_{12}) ethers with maleic acid or allyl alcohol.

4.6 Chain Transfer Agents

The total residues shall not constitute more than 0.5 percent by mass of the finished polymer. The residues of the following may be present:

a) Trichloroethylene;
b) Perchloroethylene;
c) trans Dichloroethylene;
d) Isobutylene;
e) Xylene;
f) Chloroform;
g) Mono thio ethylene glycol;
h) Tri ethylene glycol;
j) Propionates; and
k) Polyether polyol

4.7 Miscellaneous Additives

The residues of the following additives may be present:

a) Sodium carbonate and bicarbonate;
b) Sodium chloride;
c) Organopolysiloxanes;
d) Calcium and sodium phosphates and phosphoric acid;
e) Sodium dialkyl sulphonimides up to a maximum of 0.05 percent by mass of the finishedpolymer;
f) Aluminium sulphate;
g) Magnesium sulphate;
h) Sodium sulphate;
j) Calcium acetate; and
k) Sodium sulphite and sodium hydrogen sulphite.

4.8 Auxiliary Items for Working

4.8.1 *Plasticizers*

The following plasticizers may be present to the uses for which the total migration in foodstuffs including oils and fats does not exceed the maximum permitted in the standard extraction tests:

a) Adipates:

  1) Di-(normal-octyl)-adipate;
  2) Di-(2-ethyl-hexyl)-adipate;
  3) Di-iso butyl adipate;
  4) Di-decyl adipates – 30 percent *Max* in finished polymer; and
  5) Di-iso-nonyl adipates – with level of 5 percent (weight) and film thickness not exceed 1.5 mm for food product with product not exceeding fat and oil content beyond 40 percent (weight).

b) Sebacates:

  1) Di-(normal-octyl)-sebacate; 2-ethyl-hexyl)-sebacate;
  2) Di-n-butyl sebacate; and
  3) Di-octyl Sebacate (DOS).

c) Azelates:

  1) Di-n-octyl-azelate;
  2) Di-2-ethyl-hexyl-azelate; and
  3) Di-n-hexyl azelate.

d) (2-ethyl-hexyl)-diphenyl-phosphate.

e) Citrates:

  1) Acetyl-tributyl-citrate;
  2) Stearyl (mono, di, tri) citrate;
  3) iso Propyl (mono) citrate;
  4) Triethyl citrate; and
  5) Tri Butyl Citrate (TBC).

f) Esters of alkyl sulphonic acids of phenol and/or cresol C_{12} to C_{20}.

g) Polyesters obtained from di-acids like adipic, azelaic, glutaric, sebacic,

h) succinic acids and polyols (excluding ethylene-glycol and 1, 3 propylene glycol). The terminal group may be esterified with:

  1) Acetic acid;
  2) Coconut oil tally acid;
  3) Octyl alcohol; and
  4) Decyl alcohol.

j) Epoxidized oils:

1) Epoxidized castor oil *Max* 5 % to be used	Not less than 2.5 % of oxirane of oxygen and less than 6 % of iodine value.
2) Epoxidized Linseed oil *Max* 10 percent	-do -
3) Epoxidized Soyabean oil, *Max* 8 percent	-do -
4) Chlorinated paraffin Hydrogenated poly butane	

k) Glycerol, pure and glycerol triacetate;

m) Glycerol esters of saturated and unsaturated natural fatty acids;

n) Triethylene and polyethylene (Molecular mass greater than 400) glycols;

p) P-tert-Butylphenyl salicylate; and

q) 1,2 cyclohexane dicarboxylic acid diisononyl ester.

4.8.2 *Stabilizers*

The following stabilizers may be present in the finished polymers to the extent of permitted limits:

a) Organic derivatives of tin:

  1) Acid-butyl-thiostanic (Maximum 0.5 percent);
  2) Di-n-octyl-tin-di-laurate;
  3) Di-n-octyl-tin-di-maleate;
  4) Di-(n-octyl) bis (methyl-1-heptyl) oxy-carbonyl-methyl-thiotin;
  5) Di-(n-octyl) bis (methyl-1-heptyl) oxy-carbonyl-phenyl-thiotin;
  6) Bis (ethyl, 2-hexoxy-carbonyl-methyl-thio) di-n-octyl tin;
  7) Bis (ethyl, 2-hexoxy-carbonyl-phenyl-thio) di-n-octyl tin
  8) Di-n-octyl (tin s-s' bis iso-octylmercapto acetate);
  9) Bis (ethyl-2 hexoxy carbonyl methylthio) di-m-octyl tin; and
  10) Di-n-octyltin-s-bis, iso octyl mercapto acetate.

The above organic salts of tin may be used up to a maximum total dose of 1.5 percent of which the content of di-n-octylic derivatives of tin are at least 95 percent. If these derivatives of tin are used, the maximum doses of the other liquid auxiliary items should be limited to 1.5 percent on the whole.

b) Calcium, zinc and magnesium salts of aliphatic mono and polyacids, saturated or not.

NOTE — The finished PVC product should not contain more than 1 percent of zinc.

c) Di-phenyl-thio-urea, *Max* 1 percent by mass and 2-phenyl-indol, *Max* 1 percent by mass.

d) Manganese compounds:

  1) Manganese hydroxide; and
  2) Manganese salts of aliphatic mono and polyacids, saturated or not.

e) Di-epoxy-cycle-dodecene and Tri-epoxy-cycle-dodecene.

NOTE — The epoxidized products mentioned in (e) are limited to 5 percent on the whole.

f) The epoxidized resins obtained from 4-4' dihydroxy diphenyl alkane (bisphenol A) and from epichlorohydrine with a mass per epoxy equivalent value greater than 175 in so far as they meet the specifications concerning them.

g) Stearate, palmitate and myristate of lithium.

h) Polyvinyl-ethyl-ether.

j) N, N'-di-stearyl and/or palmityl-ethylene-diamine (*Max* 1 percent).

k) Sodium compounds carbonates phosphates, polyphosphates, stearates, laurates, oleates, myristates,
ricinoleates:

m) Esters of β-amino-crotonic acid with mono or dibasic alcohols.

n) Sorbitol, manitol, pentaerythritol and their esters with the fatty acids and sorbitan.

p) Hexanetriol.

q) Di-tert-butyl-p-cresol:

1) 2-4 dinoylphenyl, di (4-mono-nonylphenyl) phosphite with a *Max* 20 percent content of di-iso-octyl-nonyl-phenyl phosphite and products of oxidation; and

2) Thio-bis (methyl-tert-butyl-n-phenol) otherwise called 4,4’ - Thio-bis (6-tert-butyl-m-cresol).

NOTE — The above three products are limited to a total of 0.5 percent.

r) 4,4’ di-hydroxy-di-phenyl propane.

4.8.3 *Lubricants*

The following lubricants may be permitted:

a) Aliphatic fatty acids, saturated or not (C_8 to C_{20});
b) Aliphatic alcohols (C_8 to C_{20});
c) Fatty alcohols with at least 12 atoms of carbon, with a *Max* of 3 percent;
d) Amides of oleic, palmitic, myristic, stearic, ricinoleic and linoleic acids with amaximum of 0.3 percent;
e) Natural waxes;
f) Microcrystalline waxes, paraffin and paraffin oil containing less than 0.1 ppm of noxious polycyclic aromatic hydrocarbons;
g) Polyethylene waxes;
h) Esters of montanic acids with glycol or 1, 3 butane dihydric alcohol;
j) Esters of saturated aliphatic acids (C_{12} to C_{24}) with monovalent saturated aliphaticalcohols (C_{12} to C_{20}) with a maximum of 3 percent;
k) Esters of glycerine with fatty acids, saturated or, not, with a maximum of 3 percent;
m) Esters of polyethylene glycol;
n) Esters of polypropylene glycol;
p) Polyethylene and polypropylene glycols;
q) Esters of sorbitol and sorbitan with fatty acids, saturated or not C_8 to C_{20};
r) Edible vegetable oils;
s) Products of condensation of ethylene oxide with fatty acids C_8 to C_{20};
t) Butyl stearate;
u) White mineral oil (of saybolt with *Min*. 20);
v) PTFE Powder;
w) Poly propylene;
y) Petroleum wax;
z) Organo poly siloxane; and
aa) Tridesyl alcohol — max level 30 percent.
bb) Montan wax (Triglycerides);
cc) Carnauba wax;
dd) Bees wax; and
ee) Hydrogenated castor oil.

4.8.4 *Other Additives*

Copolymers, polyblends and terpolymers of styrene acrylonitrile, butadiene, and esters of acrylate, methacrylate to a maximum of 20 percent by mass of the total polymer only. For foaming of PVC or its blend, following blowing agents can be considered:

a) Azodi carbonamide — levels not exceeding 2 percent; and

b) Sodium bicarbonate (food grade).

4.9 Pigments

To be governed by IS 9833.

4.10 Fillers

a) Calcium Carbonate (chalk and natural)
b) Clay;
c) Kaolin;
d) Calcium silicate;
e) Magnesium silicate (Talc);
f) Silica;
g) Diatomaceous earth;
h) Aluminium silicate;
j) Bentonite (Colloidal clay);
k) Aluminium Hydroxide; and
m) Magnesium hydroxide.

ANNEX A

(*Foreword*)

LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE INCONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

IS No.	*Title*
IS 9833 : 2018	List of colourants for use in plastics in contact with foodstuffs and pharmaceuticals (*second revision*)
IS 9845 : 1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis (*second revision*)
IS 10142 : 1999	Polystyrene (crystal and high impact) for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification (*first revision*)
IS 10149 : 1982	Positive list of constituents of styrene polymers in contact with foodstuffs, pharmaceuticals and drinking water
IS 10151 : 2019	Polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification (*first revision*)
IS 10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
IS 10910 : 2001	Specification for polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 11434 : 1985	Specification for ionomers resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 11435 : 1985	Positive list of constituents of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 11704 : 1986	Specification for Ethylene Acrylic Acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 11705 : 1986	Positive list of constituents of Ethylene Acrylic Acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 12247 : 1988	Specification for Nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 12248 : 1988	Positive list of constituents of Nylon- 6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 12252 : 2017	Polyalkylene Terephthalates (PET and PBT), their copolymers and list of constituents in raw materials and end products for their safe use in contact with foodstuffs and pharmaceuticals (*first revision*)
IS 13449 : 1992	Positive list of constituents of Ethylene Vinyl Acetate (EVA) copolymers in contact with foodstuffs, pharmaceuticals and drinking water
IS 13576 : 1992	Ethylene Methacrylic Acid (EMAA) copolymers and terpolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification
IS 13577 : 1992	Positive list of constituents of ethylene methaylic (EMAA) copolymers and terpolymers in contact with foodstuffs, pharmaceuticals and drinking water
IS 13601 : 1993	Ethylene vinyl acetate (EVA) co-polymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
IS 14971 : 2001	Polycarbonate resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification
IS 14972 : 2001	Positive list of constituents of polycarbonate resins in contact with foodstuffs, pharmaceuticals and drinking water
IS 14996 : 2001	Positive list of constituents Modified poly (phenylene oxide) (PPO) in contact with foodstuffs, pharmaceuticals and drinking water
IS 14997 : 2001	Modified poly (phenylene oxide) (PPO) resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification

IS No.	*Title*
IS 14998 : 2001	Positive list of constituents of melamine-formaldehyde resins in contact with foodstuffs, pharmaceuticals and drinking water
IS 14999 : 2001	Melamine-formaldehyde resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water — Specification
IS 16738 : 2018	Positive list of constituents for polypropylene, polyethylene and their copolymers for its safe use in contact with foodstuffs and pharmaceuticals

ANNEX B

(*Foreword*)

COMMITTEE COMPOSITION

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Indian Institute of Technology (IIT), Delhi	Shri Anup K. Ghosh
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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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